

Calvert Hospice

Life, healing, hope.
September 7, 2005

The Honorable Robert M. Nicolay
Commissioner
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, MD 21215

Dear Chairman Nicolay:

Please accept these comments and the proposed amendments to the commentary on the "Principles to Guide the CON Program" reflected in the attached revised draft.

High quality health care is a human right not a market commodity. Folks are not in a position when they are ill or dying to "shop" for health care in a competitive market as they would for automobiles or dishwashing liquid when desire or need strikes them. Nor are consumers of health care services generally in a position to have adequate knowledge of the alternatives in providers, treatment options and services, let alone the "perfect knowledge" of market participants and services necessary to achieve the type of supply and demand curves I studied in Economics 101 that represent the benefits of competitive markets.

Because I believe that government's role is to ensure that all segments of society obtain the highest quality of care regardless of their economic status or health care condition, I believe that the Certificate of Need process should ensure (not just promote) access to those services through the appropriate allocation of authorizations to provide service consistent with the needs of the community.

Rather than assuming that the benefits of competition are of higher value in healthcare and that imposing the "inherently anti-competitive" CON is a step that should be taken only when the advantage of its use is clearly demonstrated, I believe we should proceed from the opposite perspective. Controlled market entry to serve the public interest should be modified only where the benefits of competition can be clearly demonstrated. Does unregulated market participation ensure better and more extensive health care services from birth to end-of-life for all segments of the population? Do patients and families at all economic levels have access to equal levels and qualities of care? Or does unregulated competition in a particular specialty, service or payment scheme simply import into the healthcare arena the less than desirable consequences of unequal distribution and economic stratification that we see in society generally? We have not yet seen evidence to support the proposition that unregulated market entry ensures both the highest quality and most equitable distribution of healthcare resources.

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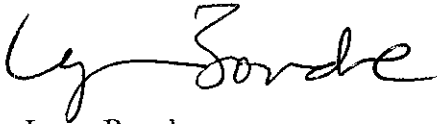


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I agree with Barry Rosen that licensure “tries to assure that people and institutions achieve passing grades, not stellar grades.” Our experience shows that licensure is virtually the regulatory system of last resort, which is called upon only when egregious problems arise.

I have proposed some edits to the commentary consistent with my less market-oriented approach, which I have attached for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Lynn Bonde". The signature is fluid and cursive, with a large initial "L" and a stylized "B".

Lynn Bonde
Executive Director

Enclosure

I. Recommendations of the CON Task Force

Principles to Guide the CON Program

Maryland's Certificate of Need program should:

- respond to its residents' needs for health care services, including hospital, long term care, ambulatory surgery, and specialized services,
- promote the quality and safety of these services,
- promote improved access to these services by underserved populations, and
- promote the affordability of health care available to Maryland residents.

Certificate of Need should be applied only in situations where unrestricted competition through normal market forces is likely to result in:

- significantly higher or unnecessary costs to the system,
- decreased access to care by vulnerable populations or less populous regions of the state, or
- a diminution of the quality or safety of patient care.

The Certificate of Need program should be:

- procedurally clear, consistent, and timely;
- flexible enough to accommodate unique situations, whether of provider mission, geography and demographics, or technological advances; and
- specific to Maryland's unique policy and regulatory framework.

The State Health Plan standards, review criteria, and associated data used to conduct Certificate of Need reviews should be kept current, and regularly updated.

Traditionally, the CON process in Maryland has been a natural component of state health planning, a process for assuring access to high quality health care services and controlling health care costs. This planning approach is based on the observation that competition and market forces do not always produce the most appropriate allocation of health care resources or the best outcomes. The CON process encompasses a fundamental review of need and resource allocation, but also brings standards to bear at the time of review that are intended to improve the quality of care and patient safety.

CON is applied to a range of different situations with somewhat different rationales:

- **Major capital investments.** Where large capital investments are involved, market forces may not appropriately match investments to community and regional needs. Because any given area has only one or a limited number of hospitals and because barriers to new competitors are high, the market for hospital services is unusual. Rather than leading to innovation and lower costs, unregulated competition may be wasteful. This use of CON addresses escalating health care costs by limiting investment when need cannot be

shown. This use of CON also addresses access to quality services by regulating the location of new facilities.

- **Services with a volume/outcome association.** When there is a well-established link between volume of specialized services and outcomes CON can be used to assure access to high quality services by attaching service volume requirements to a certificate. This process also involves an assessment of need. In the long term, surrogate quality measures like volume should be replaced by specific measures of quality and outcomes, and the up-front regulation through CON should be replaced by a meaningful, on-going licensure process that considers quantitative measures of quality and outcomes.
- **Other services.** In the case of other services, the capital investment is smaller and there is less evidence of a volume/outcome association. The rationale for CON regulation therefore must be grounded in the recognition that competition may adversely impact the optimal allocation of services among all segments of the population. In some cases, such as ambulatory surgery facilities, there are specific design issues that affect safety that may warrant review. In other cases, CON can be used to support appropriate distribution of services. ~~But ultimately for many of these other services, competition coupled with a rigorous recurrent licensure process may be a better strategy to assure high quality and good outcomes.~~

Because CON involves a careful assessment of need, it is also well suited to promote improved access to underserved populations.

The strengths of the CON process in addressing cost, quality, and access are substantial. In some cases, however, it may be determined that the impact of competition may serve to support the goals of CON. ~~but are accompanied by negative effects on competition. CON is inherently anti-competitive, limiting new entrants, limiting new investments, limiting the introduction of some services in response to emerging needs or consumer demand, and protecting current providers. Indeed, the CON statute appropriately requires an assessment of the impact of a proposed certificate on other providers and grants those providers special status in the review process. The ultimate measure of effective CON must be the impact on the interests of the citizens of Maryland, not its impact on current providers. CON should supplemented by competition only protect current providers from potential competitors when there are strong and convincing public interest arguments.~~